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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,795	08/30/2006	Jim Radmer	6710.204-US	8985

23650 7590 05/04/2009

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EXAMINER	
VU, QUYNH-NHU HOANG	

ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
05/04/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/566,795	RADMER ET AL.	
	Examiner	Art Unit	
	QUYNH-NHU H. VU	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 8-32* is/are pending in the application.

4a) Of the above claim(s) *12-20,23 and 28-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,8-11,21,22 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Amendment filed on 2/17/09) has been entered.

Claims 1, 3-6, 8-11, 21-22, 24-27 are present for examination.

Claims 12-20, 23, 28-32 are withdrawn.

Claims 2, 7 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The limitation "locking means for locking the transcutaneous device in the retracted position after a single reciprocation of the transcutaneous device from the initial position to the extended position and to the retracted position" does not disclose in elected Species 3 of Figs. 13-18.

As noted that, Applicant discloses the limitation above in Figs. 23 (non-elected Species) but not in elected Species of Figs. 13-18.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-6, 8-11, 21-22, 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Lavi et al. (US 2002/0055711).

Regarding claims 1, 10-11, and 27, Lavi discloses a medical device, comprising: a lower mounting surface 16 adapted for application towards the skin of a subject,

a sheet member 10 extending peripherally relative to the mounting surface and having a lower adhesive surface/coupling means 17 for securing the mounting surface relative to the skin,

a transcutaneous device 1 or 2 adapted to penetrate the skin of the subject and being mounted for movement between an extended position (Figs. 8 or 11) in which the transcutaneous device projects relative to the lower mounting surface and a retracted position (Figs. 7 or 12-13) in which the transcutaneous device is retracted relative to the lower mounting surface;

a release 51 attached to a peripheral portion of the sheet member, the release comprising a user gripable portion 55 moveable relative to the lower mounting surface, the user gripable portion being operatable from a first condition through an intermediate condition to a second condition, whereby operation of the user gripable portion 55 from the first to the intermediate condition causes the transcutaneous device to be moved from the extended position to the retracted position, and operation of the user gripable portion from the intermediate to the second condition causes release of an attaching means;

Regarding claims 3-5, the release means comprises transcutaneous device means (needle) operatable between a first state in which the transcutaneous device projects relative to the lower surface (Figs. 8, or 11) and a second state in which the transcutaneous device is retracted relative to the lower surface (Fig. 7, 9, 12-13), the transcutaneous device retraction means being moved between its first and second states when the user gripable portion is operated from the first to the intermediate state.

Regarding claims 6, 8-9, the transcutaneous device retraction means comprises a flexible strip portion arranged below a portion of the transcutaneous device, whereby the flexible strip portion 51 will lift the transcutaneous device from the extended position (Figs. 8, 11) to the retracted position (Fig. 9, 12-13) when the user gripable portion is operated from the first to the intermediate state; the locking means (including 35, 44, 53, 54) for locking the transcutaneous device in the retracted position after a single

reciprocation of the transcutaneous device from the initial position to the extended position and to the retracted position.

Regarding claim 21, similarly to rejection above, an actuation means is considered as element 40 comprising a first user gripable portion 42 moveable relative to the mounting surface, the first user gripable portion being moveable to cause the transcutaneous device to be moved from the initial position (Figs. 7, 10) to the extended position (Figs. 8, 11); a release 50, 51 attached to a peripheral portion of the medical device and comprising a second user gripable portion 55 being moveable to cause the transcutaneous device to be moved from the extended position to the retracted position, the release further allowing pulling force to be applied to the peripheral portion of the medical device to thereby remove the medical device when secured to the skin site, where the release is attached to a peripheral portion of the sheet member; wherein an initial state, the first user gripable portion 42 at least partially covers the second user gripable portion, such that the second user gripable portion is exposed when the first user gripable portion is moved to cause the transcutaneous device to be moved from the initial position to the extended position.

Regarding claims 21, 25, similarly to rejection above, Lavi further discloses the release means (including 50, 51, 55, 53, 56, 57) can be not actuated before the actuation means 40 has been actuated and wherein the release means is attached to a peripheral portion of the sheet member.

Claims 1, 3-5, 8, 10-11, 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sandstrom et al. (US 6,613,015).

Sandstrom discloses a medical device, comprising: a lower mounting surface adapted for application towards the skin of a subject,

a sheet member 8 extending peripherally relative to the mounting surface and having a lower adhesive surface for securing the mounting surface relative to the skin,

a transcutaneous device 2 adapted to penetrate the skin of the subject and being mounted for movement between an extended position (Figs. 1-2) in which the transcutaneous device projects

relative to the lower mounting surface and a retracted position (Fig. 4) in which the transcutaneous device is retracted relative to the lower mounting surface;

a release 34 attached to a peripheral portion of the sheet member, the release comprising a user gripable portion 46 moveable relative to the lower mounting surface, the user gripable portion being operatable from a first condition through an intermediate condition to a second condition, whereby operation of the user qripable portion from the first to the intermediate condition causes the transcutaneous device to be moved from the extended position to the retracted position, and operation of the user gripable portion from the intermediate to the second condition causes release of an attaching means; a coupling means considered adhesive member.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lavi or Sandstrom.

Lavi or Sandstrom discloses the claimed invention except for the metallic needle comprsing an outer smooth coating of a polymeric material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to providing a smooth coating of polymeric material (for example: Teflon or hydrophilic materials, since it was known in the art that smooth coating of polymeric material for easy insertion.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would

have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 21-22, 24-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-52 of U.S. Application Nos. 11/326550, claims 1-14 of U.S. Application Nos. 11/407647 and claims 1-47 of U.S. Application Nos. 11/411081. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are not structurally distinguishable from the claims in the patents.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-6, 8-11, 21-22, 24-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763